UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANDOZ, INC., RAREGEN, LLC,	**CIVIL ACTION NUMBER:**
Plaintiffs,	**3:19-cv-10170-BRM-LHG**
v.	**PRELIMINARY INJUNCTION HEARING**
UNITED THERAPEUTICS CORPORATION, SMITHS MEDICAL ASD, INC.,	
Defendants.	

Martin Luther King Building & U.S. Courthouse
50 Walnut Street, Newark, New Jersey 07101
Tuesday, December 10, 2019
Commencing at 10:50 a.m.

B E F O R E: **THE HONORABLE BRIAN R. MARTINOTTI, UNITED STATES DISTRICT JUDGE**

A P P E A R A N C E S:

ALSTON & BIRD, LLP
BY: JENNY R. KRAMER, ESQUIRE
90 Park Avenue
New York, NY 10016
For the Plaintiff Sandoz, Inc.

ALSTON & BIRD, LLP
BY: MATTHEW D. KENT, ESQUIRE
One Atlantic Center
1201 West Peachtree Street
Atlanta, GA 30309
For the Plaintiff Sandoz, Inc.

Megan McKay-Soule, Official Court Reporter
megansoule430@gmail.com
(215) 779-6437

Proceedings recorded by mechanical stenography; transcript produced by computer-aided transcription.

APPEARANCES CONT'D

QUINN, EMANUEL, URQUHART & SULLIVAN, LLP
BY: ETHAN GLASS, ESQUIRE
THOMAS D. PEASE, ESQUIRE
PETER CALAMARI, ESQUIRE
MIKE BONANNO, ESQUIRE
51 Madison Avenue
New York, NY 10010
For the Plaintiff Raregen, LLC

WILLIAMS & CONNOLLY, LLP
BY: JONATHAN B. PITT, ESQUIRE
CHRISTOPHER T. BERG, ESQUIRE
EDWARD BENNETT, ESQUIRE
SEAN M. DOUGLASS, ESQUIRE
725 Twelfth Street NW
Washington, DC 20005
For the Defendant United Therapeutics Corporation

BLANK ROME, LLP
BY: STEPHEN ORLOFSKY, ESQUIRE
MICHAEL DARBEE, ESQUIRE
ADRIENNE C. ROGOVE, ESQUIRE
300 Carnegie Center, Suite 220
Princeton, NJ 08540
For the Defendant United Therapeutics

KILPATRICK TOWNSEND & STOCKTON
BY: PETER M. BOYLE, ESQUIRE
GRETCHEN RANDALL, ESQUIRE
MEGHAN HANSEN, ESQUIRE
CHRISTINA E. FAHMY, ESQUIRE
FREDERICK L. WHITMER, ESQUIRE
607 14th Street, NW, Suite 900
Washington, DC 20005
For the Defendant Smiths Medical, ASD, Inc.

(PROCEEDINGS held in open court before The Honorable BRIAN R. MARTINOTTI, United States District Judge, on December 10, 2019, at 10:50 a.m.)

THE COURT: Welcome everyone. Good morning. First, thank you for accommodating the venue change. Much appreciated.

Before we get started, would conversation help?

MR. GLASS: Yes, Your Honor.

THE COURT: Can you pick two a side to come in chambers?

MR. KENT: Your Honor, would you like outside counsel?

THE COURT: Two lawyers on each side. Can we do that?

MR. BENNETT: Of course, Your Honor.

(A short recess occurred.)

THE COURT: Good morning again, counsel.

We did have a quick conversation in chambers. It does not appear at this point we are going to be able to make any progress. That being said, I did put a text order on the docket indicating you have a half hour each for your arguments with 15 minutes. You can use your time putting your appearances on the record or we can just go. Anyway, go ahead. Appearances for the record, please. I was teasing. You could all be seated.

MR. GLASS: Thank you, Your Honor. On behalf of RareGen, my name is Ethan Glass. With me at counsel table is Thomas Pease and Mike Bonanno. Also, Peter Calamari is here on behalf of RareGen with the clients.

THE COURT: Thank you.

MR. KENT: Good morning, Your Honor. Matthew Kent from Alston & Bird on behalf of plaintiff Sandoz, Inc. And I'm joined today by Ms. Kramer, Ms. Thompson, and Mr. Parente also of Alston & Bird. And I have two client representatives also present.

MR. ORLOFSKY: Good morning, Your Honor. Stephen Orlofsky, Blank Rome, LLP, on behalf of United Therapeutics Corporation. With me today, Your Honor, are my colleagues from Williams & Connolly, Jonathan Pitt, Edward Bennett, Sean Douglass, and Christopher Berg. Also of Blank Rome, Adrienne Rogove and Michael Darbee.

THE COURT: Thank you.

MR. BOYLE: Your Honor, Peter Boyle for Smiths Medical ASD. With me today are my partners Fred Whitmer and Christina Fahmy. We also have here in the courtroom Gretchen Randall who is general counsel of Smiths Medical and Meghan Hansen who is associate general counsel.

THE COURT: Okay.

Counsel.

MR. GLASS: Your Honor, may I take my cell phone to

keep track of time?

THE COURT: Sure.

MR. GLASS: Your Honor, may I also approach? We have copies of our slides.

THE COURT: Okay.

MR. GLASS: Your Honor, again, Ethan Glass on behalf of plaintiff RareGen.

Your Honor, we're not going to present the slides on the screen. We are not as technologically capable as the other parties.

THE COURT: Okay.

MR. GLASS: But we have provided copies of the slides to the defendants.

Your Honor, we have also talked with the defendants about confidentiality, and we have come to an agreement that the slides that we're showing today and the evidence presented may be presented in open court, and it may be provided to everybody's client with the exception being any numbers relating to price.

THE COURT: Okay.

MR. GLASS: So we're not going to orally state the numbers, but I will point you -- if I have a number I want to show you -- in the slides.

THE COURT: Okay.

MR. GLASS: Thank you, Your Honor.

THE COURT: That's agreed by both sides?

MR. BENNETT: Yes, Your Honor. With the addition of talking about patient population size.

THE COURT: Okay.

MR. GLASS: Your Honor, as we stated in our brief, and as the defendants have failed to contest --

THE COURT: Where is the irreparable harm to your clients as we stand here today?

MR. GLASS: Thank you, Your Honor.

Your Honor, there has been irreparable harm to date, but there would also be irreparable harm going forward. So the irreparable harm going forward, which would be remedied by a preliminary injunction, is the harm to our client's goodwill. It's the harm --

THE COURT: How?

MR. GLASS: Because the way that generic supply works is that the purchasers were -- for this drug is only two pharmacies, CVS and Accredo. The purchasers are desperately focused on supply guarantee. So the number one consideration when you're selling a generic is that you can --

THE COURT: You can supply all the drugs that they need. The problem is delivering it to a patient --

MR. GLASS: Correct, Your Honor.

THE COURT: -- which is out of your control. It's not like your factory can't produce the drug.

MR. GLASS: That's correct, Your Honor.

THE COURT: Okay. How does that transcend into your reputation?

MR. GLASS: So our reputation is hurt because we have gone on to market with the drug that we can make.

THE COURT: Right.

MR. GLASS: We approached both specialty pharmacies in late 2018 to have supply contracts. In those discussions, the specialty pharmacies told us that all we needed was the drugs. They had pumps. They had cartridges. We told them we were going to be able to solve the drug issue for them. They told us they had pumps and cartridges available.

THE COURT: Right.

MR. GLASS: Then --

THE COURT: Through no fault of you or your client, there's no cartridges and pumps.

MR. GLASS: That's right. And so the problem now is that these specialty pharmacies, whether it's our fault or not --

THE COURT: Right.

MR. GLASS: -- are skeptical that we're going to be able to deliver on our promises to make the drug available.

THE COURT: Well, how can you say that when part of your papers talk about the fact that the defendants really put pressure on these pharmacies to exclude you from the market?

And then they're going to turn around and say you can't produce for us when they were complicit in this, perhaps?

MR. GLASS: Yes, Your Honor. Because they'll make the same arguments to the specialty pharmacies that they've made to Your Honor, which is that we should have anticipated the anticompetitive conduct. We should have had pumps and cartridges arranged before we launched, and because we didn't it's our fault. And then it's just a debate with the specialty pharmacies. On one hand, we've got the defendants telling the specialty pharmacies it's our fault. On the other hand, we're telling the specialty pharmacies it's their fault. All the while the defendants are supplying both pumps and cartridges.

THE COURT: But the specialty pharmacy says to you we just need your product. We have a method of delivery. And then they say to you we don't have a method of delivery anymore because of what they did. You should have thought about this the same way they did, to arrange this arrangement or to get into this arrangement, and that's your fault, even though we, the pharmacy, said we had a method of delivery?

MR. GLASS: So there's two other parties involved in this.

THE COURT: Okay.

MR. GLASS: I don't want them to get lost.

THE COURT: Okay.

MR. GLASS: We've got prescribers and we've got patients.

THE COURT: Right.

MR. GLASS: That's in addition to the specialty pharmacies. So even if we are able to persuade the specialty pharmacies that it's their fault, while they're telling us it's our -- they're telling the specialty pharmacies it's our fault. We need prescribers to prescribe the generic. We need payers to put on their formularies the generic, and we need patients to not push back on the prescribers about the generic. And those are all parties that have no idea that there was this scheme.

THE COURT: Are they part of this lawsuit?

MR. GLASS: No, they're not part of this lawsuit.

THE COURT: So I come back to how's this harming you, aside from the fact that your company isn't able to sell the product and receive money for your product?

MR. GLASS: Because -- let me give you an example. If we receive the injunction today and we had access to cartridges, that would solve our cartridge problem. But we would need to go to the prescribers and explain to them what has happened over the past nine months since they thought we were going to be able to launch but couldn't.

THE COURT: Does a prescriber actually write a prescription for a generic, or does a prescriber write the

prescription and then you go to the pharmacy and the pharmacy says we have the generic, or you get into an intermediary that says, you know, the generic is X, the branded is X to the second power?

MR. GLASS: This is why the payers, the insurance companies are important because it starts with them. The payers have a formulary which are the drugs that are covered by their insurance policies. The payers will require mandatory substitution for certain drugs meaning that when you or I go to the pharmacy to fill our prescription, the pharmacy will have to substitute to the generic, regardless of how the prescription is written.

THE COURT: Okay.

MR. GLASS: The doctors can check a little box called "dispense as written" to override that. And so what we need is we need everybody in this ecosystem to understand that we have secure supply. We need the insurers to put us on their formulary, which they have not because we are unable to launch in subcutaneous. We need the insurers to say that there's mandatory substitution, which they will only do if there's insured supply. We need the doctors to not check "dispensed as written," and we need the specialty pharmacies to actually stock and dispense.

The problem with the theory that the specialty pharmacies know what's going on is that they're only one piece

of the entire puzzle, and that's irreparable injury because but for the unlawful restraints, we would have launched and everybody in the ecosystem would have been able to test our product, see whether or not it should be on formularies, see whether or not doctors want to prescribe it or mark it "dispense as written." But now, nine months later, there's been a significant diminution of our good will. And we can regularly interact with the prescribers. We have day-to-day meetings with the prescribers so that they don't check "dispense as written." We meet with the insurers so they put us on their formulary. And so that's been a significant irreparable injury. That continues on. And what we know is that at some point there's a tipping point. At some point the prescribers and the insurers and the specialty pharmacies and the patients give up on the generic supplier. And so our concern is that that tipping point is in the near future where even if we got access to cartridges, they will have written us off. And we have a good example of that. Another PAH drug, which uses a different approach called Flolan --

THE COURT: That was a manufacturing issue, wasn't it?

MR. GLASS: It was, but the problem is --

THE COURT: It was their manufacturing plant.

MR. GLASS: But the patients and the prescribers --

THE COURT: But it was their own fault. I mean, this

is -- there's a third party -- I'm saying it, but I don't mean it -- to blame here.

MR. GLASS: There is but nobody knows that. This has all been confidential. The reason we asked for discovery from Your Honor is because we approached the specialty pharmacies and they told us no problem. We started talking with them about contracts. Then all of a sudden they told us, actually, we can't stock you. That's the only interaction that alerted us to this conduct. Everything has been secret. There's been nothing that's been publicly announced. Nothing made public through this litigation. There's a protective order, and so if we go and we tell the insurers and the payers and the patients actually it was their fault, they're going to say, we don't know that. There's no evidence of that.

And that's the core problem with our irreparable injury is that every day that goes by, they win. Because not only do they get the millions of dollars of overpayments by patients, but they also reduce incrementally the prospect that we will succeed.

THE COURT: So let me ask you the question, which really is looming. How come, when they knew what was going to happen in 2015, and they reacted, how come your client didn't react the same way or act as quick?

MR. GLASS: So Mr. Kent will speak specifically to the Sandoz issues. But I'll tell you, Your Honor, that we

didn't know that they were going to corner the market on cartridges. In fact, from my client's perspective, RareGen's perspective, we were talking to the specialty pharmacies in late 2018, and there was no such restriction. What defendants like to cite is an end-of-life notice for the pump. This isn't a pump case. We're not here to talk about the pumps. We understood that the pumps that were in Accredo's possession were owned by Accredo and available to use with whoever Accredo dispensed it with.

So the idea that 2015 and 2016 we had any notice is fiction. The first we learned of it, the first we learned of it, the first we learned of it was when Accredo and CVS changed abruptly in late 2018, and said, we can no longer talk with you about stocking your drug. That's when we said, oh, my gosh, something has changed in the market. We approached UT and Smiths to try to resolve this, and then we sued in April. So there was no delay and there was diligence.

We also, Your Honor, right when we heard that there was an issue, started working on alternatives. So we were reaching out to alternative pump suppliers. We were reaching out to alternative cartridge suppliers. We wouldn't be here today if we had an alternative pump or cartridge to offer the market.

THE COURT: And you're still pursuing that avenue?

MR. GLASS: We're still pursuing that, Your Honor, to

this day. We have a third party who we're working with that we expect will be able to make cartridges for us eventually, but we don't have any cartridges today and there's no imminent cartridge launch.

Your Honor, one more thing on irreparable injury, if I may, and then I'll be happy to answer any more questions Your Honor has.

We had a 180-day exclusivity period. The 180 exclusivity period is statutorily granted to the first ANDA filer. I'm sure Your Honor has had Hatch-Waxan cases and knows that when the party who challenges the patent prevails in court, that party gets 180-day exclusivity. We got that on a -- based on a settlement.

THE COURT: Right.

MR. GLASS: Your Honor --

THE COURT: So you're saying they entered that settlement with unclean hands because they knew, notwithstanding what the agreement was when you were going to go to launch, you couldn't launch because there was no way to deliver your product?

MR. GLASS: So from my third-party perspective because RareGen was not a party to that, yes. I'll let Sandoz specifically discuss what Sandoz expected. But when I look at that contract and the contract says you may launch on this date, but they knew that when we got close to launching that

they were going to incumber our launch by making the cartridges unavailable, that is not good faith, Your Honor.

And Your Honor, that just goes back to there isn't a lack of diligence. Sandoz could reasonably expect that if there was a contractual provision that said that it could launch, that there wouldn't be any impediments placed by the parties to that settlement agreement.

And Your Honor, the 180-day exclusivity period has expired. It started and it has expired. That's irreparable injury because the way generics also work is that the 180 exclusivity grantee, the party that has the right to be the exclusive generic, almost always has an advantage over the other generics. Because like the brand, being able to get in with the doctors, get in with the insurance companies, get in with the specialty pharmacies and get in with the patients, there's a reluctance to switch. And that is gone. We will never get that back.

So that's an irreparable injury that continues for us, in addition to the incrementally diminishing possibility that we can even succeed.

THE COURT: I took you off track. I probably got to some of what you wanted to talk about.

MR. GLASS: For sure, Your Honor.

THE COURT: Okay.

MR. GLASS: So, Your Honor, just to conclude about

the non-likelihood of success factors. So RareGen and Sandoz are suffering monetary damages. That we don't dispute. But we also have this irreparable injury component that has happened and continues.

On the other hand, if the injunction is granted, there is no irreparable injury to the defendants. So when we're talking about an injunction, we're looking at the but-for world. The but-for world is Your Honor grants the injunction, they just have to compete. They have to provide better quality products and lower prices to keep us from gaining their customers. That can't be irreparable injury. That can't be injury at all. That's a benefit.

THE COURT: Well, what is the status of these pumps and cartridges right now? Who owns them?

MR. GLASS: So, Your Honor, it depends on which pumps you're talking about.

THE COURT: Right.

MR. GLASS: So for pumps, our understanding is Accredo, the largest specialty pharmacy, which has a significant portion of the patients that it cares for, has enough pumps to service all of its patients. Those pumps are unencumbered by defendants. So those are the pumps that we would use with Accredo's permission to the patients who are using the generic treprostinil.

THE COURT: Absent the agreement.

MR. GLASS: Absent the agreement.

THE COURT: Okay.

MR. GLASS: There are also pumps that are under defendant's control, which we're not talking about in our case. We're not talking about here.

THE COURT: They own or they control.

MR. GLASS: That they control them and they can use them, and we're not asking for the injunction to apply to those pumps.

THE COURT: Okay.

MR. GLASS: Cartridges, the way that cartridges worked before the restraints was that a specialty pharmacy would place an order to Smiths to purchase cartridges. That order would then be filled, no questions. Just you need 2,000 cartridges, we're going to fill them.

Now, the way that the cartridge supply works, is that specialty pharmacies places an order with UTC, and UTC makes sure that the specialty pharmacies are not using those cartridges for a generic. Once UTC is comfortable that the specialty pharmacies are only using it for Remodulin®, then UTC will sell them the cartridges.

THE COURT: Who owns those cartridges?

MR. GLASS: UTC does.

THE COURT: And how about if UTC says we'll sell you these cartridges, but as double what the market price has?

MR. GLASS: Your Honor, I don't want to speak for my clients, but I'm sure they would take that. I -- I have no doubt that my client would buy cartridges from UTC at a hefty premium to what UTC paid for them.

Your Honor, again, I haven't consulted with my client.

THE COURT: You want to go back in the conference room?

MR. GLASS: I mean, Your Honor, it shows you how important the cartridges are. I don't want to negotiate for my client, but I'm not sure there's any number you can tell me today that I wouldn't take back to my client and we would have a very serious discussion of paying that.

Now, Your Honor, the balance of harms and important part -- and this goes to irreparable injury in a very unique way for this case. There is an irreparable injury to the public as well. So this normally goes under the public interest prong. The public interest prong is normally a throwaway in preliminary injunction cases that's tacked on to the end. Here, the public interest prong is paramount. The public interest is in having access to all of the competing drugs. That is undisputable. The public has an interest in being able to choose between the Remodulin® product and plaintiff's generic product. The public has an interest in the competition that the generic product brings to Remodulin®.

THE COURT: Well, the public interest isn't that they

can't get the drug because clearly there are -- they're getting the drug, albeit at a higher cost, perhaps. And there are three other methods that they can get the drug, albeit not the preferred method of having the drug administered, correct?

MR. GLASS: Respectfully, Your Honor, no.

THE COURT: Okay. Tell me why.

MR. GLASS: Let me start with, yes, patients can get access to Remodulin®. There is no dispute that patients can, at a 98 percent margin.

THE COURT: Okay.

MR. GLASS: So in the annual report -- if Your Honor will please turn to slide 12. In UTC's annual report, it states exactly how much revenue and profit it gets from Remodulin®. $599,000,000 in revenue on 584.9 million in profit.

THE COURT: Okay.

MR. GLASS: What would happen is patients and payers would significantly benefit from the entry of a generic because that gross profit number, even if Remodulin® kept all 100 percent of its patients, would go down.

How do we know that? Because on slides 13 and 14, we have evidence from discovery on what the response was by the mooted, just the mere threat of RareGen and Sandoz entering. So this is the part where we've agreed with the defendants not to say in open court.

THE COURT: Okay.

MR. GLASS: But you can see from this testimony, this is the president of UTC. The president of UTC testified that they increased price in 2018, and they decreased price in 2019. And the factor for decreasing price instead of increasing price was the mere shadow of us entering.

So that's where the public would benefit is again going back to that $585,000,000 in profit, if that went down, that money doesn't come to us. That money goes to the public.

THE COURT: Right. And again, just so I'm clear, the public is still getting this drug, albeit at a higher cost. It's not like the drug isn't available. And if they can't get the drug through this method of administration, there are other ways that it can be administered, albeit not the preferred way.

MR. GLASS: Right. So I'll address the oral and pill in one second, Your Honor.

THE COURT: Right.

MR. GLASS: So access -- we don't have any evidence that patients who need PAH treatments aren't getting access. So I want to tell Your Honor we've had very limited discovery. So we don't have that evidence. But I will tell Your Honor that there are patients who cannot afford the drug. This happens in every case where when the generic enters, the number of patients on the treatment expands.

THE COURT: Okay.

MR. GLASS: The reason why is that when you have a brand -- and I'm not good at math so I won't do the math for you. But you can divide the 600,000,000 in revenue by the number of patients to see what the cost is per treatment, per patient.

THE COURT: Okay.

MR. GLASS: Part of that is paid for by insurance companies. Part of that is paid for by the patients themselves.

We know that there are patient assistance programs that help lower means, patients, to get access to the drugs. In fact, UTC has a patient assistance program, it's on slide 14, that when we were even threatening to enter, they improved the benefit on the patient assistance program by a hundred percent. They cut the amount that the patients had to pay out of their own pocket.

But there are two important things to note. It's still not zero, and there are patients who cannot even afford the amount that the patient assistance program offers. And there are patients who UTC deems counteracts as the patient assistance program and don't get the benefits. So I don't want to represent that we've got evidence from discovery because it's been limited. But I will tell Your Honor that in the generic cases, which I've litigated many of, as have my

co-counsel, when the generic enters the number of patients covered by the treatment expands, that expansion are patients who are today unable to get on the preferred treatment. Okay.

Now I'll do the three other routes. I really want to address your question on the three other routes. What does that mean for those patients? Well, it's possible that they're going untreated, but it's unlikely.

THE COURT: Okay.

MR. GLASS: The more likely is that they're being treated by a less preferred drug. It could be one of the other three routes. So there's intravenous, there's oral, and there's inhaled. It's possible that some of those patients --

THE COURT: And they all are either not as effective or bring other inherent risks to the patient rather than this type of delivery?

MR. GLASS: Exactly, Your Honor. So a physician, not us, not UTC, makes the determination which route of administration is best for that patient. And it's patient by patient. There are some patients that just -- inhaled works best. There are some patients that can't tolerate the pain of injections. There are some patients who are so sick that inhaled and oral just doesn't work.

And so this is a physician decision. So the physicians are making the treatment decisions based upon what's best for the patient. The position the defendants are taking is that a

physician can't prescribe the preferred route of administration for a particularly sick patient and must prescribe oral or inhaled if they want a lower price. And that's just not right. It's not right. Physicians should be free to prescribe the best administration for the patients. And the physician shouldn't be put in the very difficult position of saying, I'm asking the patient to pay more than they should or the insurer to pay more than they should, and therefore I'm going to have them do a less preferred.

Even between IV and subcutaneous, there is very little switching. So on slide 15, we have testimony from the president of UTC. He testified that there's very little switching from IV to subQ. He testified the more likely is the other way around, subQ to IV. And it makes sense. There are a lot of downsides to subQ and would only be if the patient really needs it. Most importantly there's a lot of site pain. There are also a lot of downsides to IV. Most importantly, sepsis, a deadly condition. So physicians make a determination on what's the best drug and what's the best route of administration.

And if I may, Your Honor, the argument the defendants make that PAH patients have all kinds of other ways they can be treated, it just really doesn't help in an antitrust case. In an antitrust case we don't consider every possible substitute. We only consider reasonable substitutes. So in

this case, it wouldn't be enough that bed rest would help a PAH patient. That doesn't make it a substitute. It's not enough that some PAH patients benefit from aspirin. And it's not enough that some PAH patients are currently untreated or are on oral, IV or inhaled. Since the doctors would put them on subcutaneous, and that's where they would get the distinct benefit of our competition.

It's not just subcutaneous where they benefit from our competition, though. IV patients benefit from our competition once we get cartridges. I'm going to take a second because this is a little hard to explain. We're currently offering IV. Plaintiffs offer IV. However, to get on the formulary for the insurance companies, and get the insurance companies to say must substitute, and to get prescribers on board with the generic, we also have to be on subQ. We have evidence of that. We've put it in as a declaration, but it's in slide 16, that our entry, even into IV has been muted because of our inability to provide a subcutaneous option.

Physicians do not want to have to say, oh, the Remodulin® substitute is only built for IV because they just want to be able to prescribe generic or not.

Insurance companies are about simplicity and efficiency. They don't want to have to determine whether or not a person is prescribed for subQ for IV or whether they're prescribed for subQ or IV based upon some other sort of

payment avoidance. So they've told us that we will not go on a repertory -- we will not go on a formulary until we have a subQ available product. And so Your Honor, we're being blocked not only from subQ, but really from IV as well.

Now, defendants have said we've brought all this on ourselves. That we should have done more diligence. I've already discussed with Your Honor that we didn't know this would be a problem until the beginning of this year.

Defendants have also said, well, you shouldn't have launched an IV. But that also says that we shouldn't provide any patients with a lower cost alternative. That was not palatable to Sandoz and RareGen. Sandoz and RareGen launched an IV so that at least some patients could get the benefit of choice. Even if it was imperfect and even if it was muted, we were not going to hold back our IV product just to make this case better. Just to be able to tell Your Honor that we have a great preliminary injunction. Not even to preserve 180-day exclusivity.

So this is really about patients. We're trying to serve patients. We're trying to get that profit down, which is a return directly to patients in the healthcare system.

And, Your Honor, I know my time is getting short, so I won't spend too much time on this, but that is exactly what defendants are worried about. If we come on the market and we compete with them, they will lose the Remodulin® franchise,

which would be devastating. And you know what? I don't blame them. It's been a great run. They had patents. They're making 98 percent profit. They're charging whatever they want. They're able to put in their annual reports that they're making almost 600 million dollars. But, Your Honor, the patent is over. They cannot use the anticompetitive conduct to extend the patent. They can't continue to block the generics from being able to approach this patient population.

But as you'll see in the slides that start my presentation, that's exactly what they intended to do, and that's exactly what they did. And the way that they did was despicable. They went to the specialty pharmacies, and they told the specialty pharmacies you will not get any more cartridges until you sign these exclusivity agreements.

So Your Honor asked why, you know, we don't have specialty pharmacies or insurers or patients as parties here. Because none of them have done anything wrong. It's a hundred percent the conduct of defendants that have blocked us from this market. They did so by threatening to withhold cartridges, which the president of UTC admitted -- on slide 4 -- was negotiating leverage to get the specialty pharmacies to sign the contract that blocked RareGen and Sandoz. And it worked. Because in May and late April of this year, after we filed our case, CVS and Accredo signed the contracts saying

they will not dispense cartridges outside of Remodulin®, thus blocking us completely from the market.

So Your Honor, I implore Your Honor -- first, I thank Your Honor for the time that Your Honor's giving us today as well as providing us with discovery because virtually everything that we alleged in our complaint is true. But it's true to a more extreme than we ever thought. We never thought that the defendants would risk patient lives by withholding cartridges. We never thought that they would force the specialty pharmacies to do something they didn't want to do, and the only reason that the specialty pharmacies acquiesced is because they couldn't go out of cartridges and thus leave their own patients at risk.

We had no idea that Mr. Benkowitz and the witnesses in this case would be so candid and tell us exactly what was going on, and we had no idea they would have documents within UT Smiths that shows that this was all designed to block us from entering the market.

So Your Honor, thank you for providing us with discovery and the time today. What I would tell Your Honor is that the clock is ticking. We really need access to these cartridges, but more importantly, the public needs access to these cartridges. Thank you, Your Honor.

THE COURT: Thank you.

MR. PITT: Your Honor, may I approach to hand up --

THE COURT: Please.

THE DEPUTY COURT CLERK: Thank you.

THE COURT: So if you're just looking at this from afar, and you go back in history and there was the lawsuit that ultimately was resolved and the resolution was the generic can come to market at such-and-such a time. And meantime, there's this event that occurred, and you're buying up the means to which the generic can go to market. Optically, how does that work?

MR. PITT: Well, Your Honor --

THE COURT: The way I said it.

MR. PITT: Respectfully, the way you said it, Your Honor --

THE COURT: Doesn't look good.

MR. PITT: -- is not actually what occurred.

THE COURT: I'm just saying the way I said it doesn't look good optically.

MR. PITT: If out of nowhere --

THE COURT: There was a nefarious plan --

MR. PITT: -- not proceeded by any other arrangements, which they're trying to say the world started in late 2018.

THE COURT: Right.

MR. PITT: The world started far before then with the arrangements that my client, United Therapeutics, put into

place to ensure that their patients would have adequate pumps and cartridges when they learned that Smiths was discontinuing those items.

THE COURT: I guess your position is we had enough foresight to look forward to see what was going to happen. We wanted to protect our patients, so we fought the world and our patient's protected.

MR. PITT: Not exactly, Your Honor. It's not that we had some clairvoyant power to know what was going to happen in the future.

THE COURT: They told you what was going to happen.

MR. PITT: They told everyone what was going to happened. Sandoz indisputably was on notice. The instances -- and why don't I just go right to it. The instances of Sandoz being on notice are many. 2011 when they filed their ANDA, they expressly note that they need a cartridge reservoir for the drug in order to inject it subcutaneously.

Three years later, 2014, they receive tentative approval so they know they're going to launch the drug. What do they do at that time? Nothing.

2015, the following year, they settle the patent litigation, and they know there's an agreed entry date of June 26th, 2018.

The agreement, by the way, Your Honor, also has a

provision that expressly says that nothing in the agreement gives Sandoz any right to any pump or delivery system by a third party or by United Therapeutics. That's directly in the agreement.

It's undisputed that --

THE COURT: At that point the world knew what was happening with the pump and the cartridge.

MR. PITT: Well, certainly the customers did who had received the end of life notice. And certainly Sandoz did right after then.

2016, this email is by Yaping Zhu who -- Dr. Zhu is, I believe, the Senior Director of Device Development at Sandoz. And this email is to the leaders of the product launch. It can't be disputed that Sandoz was on notice after having signed that Hatch-Waxan lawsuit settlement.

On the topic of Hatch-Waxan, I think it's important to note a couple of things, just in response to what we've just heard. First, Your Honor, Hatch-Waxan applies very specifically to the drug. It provides no access to delivery mechanism, technology, or anything else. It's all about the drug.

THE COURT: Understood.

MR. PITT: And everyone who plans to launch a high touch drug like this, and wants to be able to launch it to a patient population that will be -- will have it administered

subcutaneously knows there is a lot of work to do to ensure that there is a delivery system in place. That is the work that my client did to ensure that its patients -- that there would be enough cartridges for its patients to use.

And now the plaintiffs come along and say, well, the world actually started in 2018. None of this stuff was here before. I can show you why that's wrong, Your Honor, and why, in fact, the provisions that they are complaining about today have always been aspects of the agreement, which was always an exclusive arrangement with Smiths whereby Smiths would produce cartridges they wouldn't otherwise have produced. Wouldn't have the charges here today to fight over if United Therapeutics hadn't made the upfront investment and assumed the risk, very importantly, for an activity that Smiths wasn't willing to continue to engage in. We did those things with the expressed understanding -- and the contemporaneous evidence all supports this -- we did those things with the expressed understanding that, of course, they would be for our patients.

THE COURT: When does being forward-thinking, good business sense, you becoming worried about your supply to service your patients, when does that cross the line and become anticompetitive conduct? Not in this case, you're going to say.

MR. PITT: I was just going to say some place beyond

what we've seen here.

Your Honor, there is evidence, and we've submitted it, that demonstrates that our client has forecasts of -- and to be clear, in the past, every time we've had forecasts about the burn rate of these cartridges, we have undershot that burn rate significantly. All of these additional instances of cartridge production are generally for two reasons. One is we did not -- we thought cartridges would be used more slowly than they were, but they fluctuate wildly, the use -- the extent of the use does fluctuate. And number two, all of what you -- what you see in these agreements is also reflective of the fact that people other than generics are trying to get these cartridges.

THE COURT: There was a point made that you didn't know where the cartridges were going. They were being used for delivery of other medications.

MR. GLASS: For antinausea medication, 88,000 cartridges. RareGen itself tried to do a bulk purchase in January 2019 of 300,000 cartridges. There are reasons why my client wanted to ensure that the original deal it struck, which involved having enough cartridges for its patients for an extended period of time because you need belt and suspenders. You need to be able to plan. You can't always know exactly when the next generation technologies are going to come online, and you can't always predict what the

fluctuations will be in the patient's use of the cartridges. And for all of those reasons, we set about ensuring that we would have a steady supply. What they want to do now is say we did none of that. And they say, well, we were bamboozled. We think actually what happened was the specialty pharmacies told us they could do it, but then they couldn't. But if you look closely, you'll see that they never asked about cartridges until January 2019 was the first time they asked about a supply of cartridges.

By the way, in early 2017, Your Honor, Sandoz wanted to test its drug. They tried to obtain just two pumps and two cartridges, and they were unable to do it. They were unable to do it because they weren't being sold on the market commercially because they had been discontinued. Again, they say they had no notice, but event after event after event demonstrates that they did.

So finally, in January 2019, they asked the question and they're told in no uncertain terms there are no cartridges for you because there is this exclusive arrangement. Those cartridges are for United Therapeutics customers.

THE COURT: So let's walk outside this courtroom now and talk about the argument that counsel made that there are real people out there that have issues that need this drug that may not be able to afford this drug, and by keeping them out of this market, you're either depriving them of a

preferred method of delivery or they're not getting any drug.

MR. PITT: There is zero evidence of that, Your Honor, and, frankly, it is simply not the case. First of all, the figures that they are using on price are -- the discounts and the like, that's not price paid by patients. That's prices paid by payers, and those are decisions that go through -- they talk about -- by the way, in describing their alleged reputational harm, they talk about the specialty pharmacies won't trust us, the prescribers won't trust us, insurers and payers won't trust us. Zero evidence of any of that in the record. Absolutely nothing in the record on any of that. They had additional depositions left over. They complain that they had limited discovery, but they had additional depositions they didn't use. For all the emphasis that they've placed on the importance of specialty pharmacies, the claim that they were threatened, which is absolutely not supported --

THE COURT: You say this is a money damage case?

MR. PITT: I'm saying it's not an antitrust case because there's no cause of action for a variety of reasons. But to the extent that one day they could demonstrate liability, then for a number of reasons, yes. Number one, what they're claiming would be compensable by monetary damages, which the cases clearly reflect. Number two, no evidence of any of what they're now claiming would occur, only

speculation by some of their own employees that they are worried that that kind of thing might occur.

You know, the -- there is even testimony from the plaintiffs in which they concede that an injunction wouldn't remedy the reputational harm that they're now claiming. But I want to actually get to another point about irreparable harm, if I may, unless you want to stay on that topic.

THE COURT: I'm curious. Counsel brought up an interesting point about the 180-day exclusivity. So they've lost that. How is that calculable? How is that repairable?

MR. PITT: Well, first of all, it's not something that they can recover for because it is self-inflicted. I say that for two reasons. The first is they did make a choice. They now have all kinds of explanations about why they did, but it is undisputed that they made a choice. There is a slide which I'm not going to show because of our agreement with counsel, but I would ask you to look at slide 15, which is a table in which Sandoz and RareGen were debating, well, what should we do and what are the financial consequences of that? And they ultimately made a decision to go for -- I know they put everything in terms of the patient, the patient, the patient. They are not nonprofit companies. They are interested in making a profit, and in that case they were interested in the short-term gain that this would afford them rather than waiting until they solved their cartridge problem

before launching.

The 180-day exclusivity would also have waited for them, but they made the decision to launch. And I don't see how they can now claim that that is irreparable harm that is compensable. In connection with that point, Your Honor, the following slide 16 here demonstrates that at the time they made that decision, that expressly acknowledged that if they went with the intravenous only plan, it would result in payers not mandating generic substitution the harm they're now claiming they're suffering. They knew all of this before they made the decision, but now they want to call it irreparable harm and say that it is somehow appropriate to upset what has been a nearly four-year arrangement for a supply that we have relied on and continue to rely on. It's simply not the case that we wouldn't be harmed if all of a sudden Your Honor were to say those cartridges that you invested in and that you assumed the risk to have made and that you have always had an understanding with Smiths were for your patients and that you've built your business plans around and your distribution chain, those are now going to be given -- or some number of them are now going to be given to another company, of course we would be harmed, Your Honor.

THE COURT: When you say "your patients," though, clearly when you were the only drug on the market, they were your patients. But now that there could be other drugs on the

market, don't your patients have a right to say I'd rather have a generic rather than a branded?

MR. PITT: Well, the patients may or may not have that right, Your Honor, but when the company that is making the generic drug is repeatedly on notice of the need to provide an administration mechanism and doesn't do it, the fact that some patients aren't able to get the generic for a certain kind of administration is not at our doorstep. And the antitrust laws don't permit a competitor who is not an equally efficient competitor to come in at the last minute and sort of say, well, gee, we need what they have. They planned for it, but we need it so now we want you to order it given to us. That's simply now how they work.

The -- just a couple of other points to touch upon some things we heard. Obviously, if Your Honor has other questions -- I also wanted to mention that Mr. Boyle, who represents Smiths, may want to also say a few words. And we only have kind of one time to stand up here, so I want to make sure that if I'm starting to push the limits of what Your Honor had in mind in terms of time, that we give Mr. Boyle some opportunity as well.

But just a couple of other points. They -- again, I would say that the -- that the alternatives that have been available to them are something that we haven't heard a lot about. But one of the reasons why it's so critical to note

that in that -- in that whole seven-year period of time when the plaintiffs were repeatedly on notice of the need to provide for this, what could they have done? Well, they could have done any number of things. They could have done what they ultimately wound up doing in May of 2019 and contracted with somebody to start manufacturing a cartridge. They claim they weren't aware of that. But the fact is, Your Honor, they had no arrangement, no agreement, no contract with somebody -- a specialty pharmacy or otherwise -- to manufacture a cartridge for them, no written commitment of this supply. This particular supply is yours, and your patients will have access to it. None of that until in May of 2019 they finally contracted with a company -- whose name I've agreed not to state in open court -- but they've contracted with a company who then, in a matter of just a few months, was able to produce a prototype. We have no visibility into why they haven't yet sold it. We asked -- all of the documents suggest that September or October was the date in which that was to occur. We have not -- we've asked for some discovery of that and they've not given it to us, so we don't really have any visibility into why now they have not yet sold it. But we do know they had also sought to make arrangements with another company. Again, I won't mention the name here. And they ultimately sent a breakup letter to that company saying we're not interested. We're going with this other company.

The cost for these things, by the way, developing a prototype was cited at around $50,000. We're not talking about a huge cost. If you'd like to see what a cartridge looks like, it's this. This is the cartridge that we are fighting over today.

I want to talk just briefly about the fact -- the sort of world not starting in late 2018 point. By the way, also many options, before I get there, of pumps, that the ability -- both experts in this case agree you can customize --

THE COURT: What was your company doing prior to this product coming on the market as far as delivery?

MR. PITT: As far as prior to the CADD MS®3 coming on the market?

THE COURT: Yes.

MR. PITT: I believe we believed we used the MiniMed. There was another pump that we used called the MiniMed, and that pump is still being used, I believe, in other countries. Could be cleared, if one wanted to try to go through the process of clearing it through the FDA, could be cleared again for use in this country.

The MS®3 itself, by the way, used to be an insulin pump. It was modified essentially with some software modifications so that it was capable of dispensing Remodulin® subcutaneously. That's what Smiths did. That's how they got the pump originally. Both experts in this case have agreed

that to do that now would involve a time period of 12 to 24 months. They both agree it could be done in that time period of a cost of around one-and-a-half to three-and-a-half million dollars. Frankly, all of which is a pretty small fraction, if you look at the following slide, which I'm not going to show in open court.

THE COURT: 22?

MR. PITT: Yes. It's a small fraction of what it would have cost or, rather, what the parties believed or what the plaintiffs believed they were going to make in just their first year of operation here.

On the point, Your Honor, of whether the world started in late 2018, I don't need to go through all of this because it's -- it is in our papers, Your Honor, but I do want to be clear that the contemporaneous evidence strongly supports the fact that this agreement has always been an exclusive arrangement between Smiths and United Therapeutics. There were amendments along the way when various things happened, when we saw cartridges flying off the shelves and we realized we needed to do something in order to honor the purpose and effect of that original agreement. But the agreement has always involved exclusivity.

You know, a quick word, I guess, on the public interest and on -- well, I guess really on the public interest in particular.

Again, I've already discussed the fact that there is no evidence that any patient is being harmed. In fact, their own employees testified that no patient is being deprived of any drug. There is no evidence in the record that any patient is actually even paying more. There is evidence about the pricing to specialty pharmacies, not to patients.

The public interest is not furthered when companies are disincentivized from having foresight and making investments and assuming risks in order to prepare for their future needs and then know that they will risk having another company, their competitor, direct competitor, come along and simply strip them of the fruits of their investment. That does not serve the public interest, Your Honor.

We've got a number of other points in our papers, but I think at this point I've really covered most of what I was intending to cover with Your Honor, but I'm glad to answer further questions or else to turn things over to Mr. Boyle to make the points that he was interested in making.

THE COURT: Okay.

MR. PITT: Thank you, Your Honor.

THE COURT: I think you have about nine minutes.

MR. BOYLE: Thank you, Your Honor. Peter Boyle for Smiths Medical. I just want to make a few points.

Smiths has been trying to wind down the MS®3 product line for five years now. The reason it's in the middle of

this case is because it did the right thing for patients by entering into a supply arrangement with United Therapeutics to extend production on both the MS®3 pump and the MS®3 cartridge.

To be clear, the pump is discontinued. Smiths stopped making that product and selling it in 2017. The cartridges, which now seem to be the focus of this case, those products would not exist today but for the arrangement with United Therapeutics and Smiths.

Counsel for plaintiffs made reference to our end-of-life notice for the pump. That went out in August 2015. They want to act like that notice did not tell customers what was going on with cartridges at that time. If you look at the end-of-life notice, Smiths told customers in August 2015 that cartridges would be available for around another three years. We submitted a declaration from Carl Stamp in connection with these proceedings. Mr. Stamp was head of marketing and business strategy at Smiths back in 2015. He clearly states in his declaration, in the absence of the UT arrangement with Smiths, Smiths would have stopped making those cartridges some time in 2018. They would not have been available for the generic launch of this product.

One of the positions that plaintiffs have taken with respect to the cartridge is the margins on the cartridge -- the gross margins were so high that in some gerrymandered

but-for world, Smiths would've just kept making these products indefinitely. That's not true. Smiths had already decided to discontinue this product.

We have evidence from Chris Quinn. We submitted a declaration from him. And Nate Walker has -- who is one of our global product managers -- gave a deposition. If you look at those pieces of evidence, Your Honor, you'll see Smiths was not going to continue making these products.

Just to put this in perspective, in fiscal year 2019, that ended in July, Smiths only made about $500,000 in revenue. That's top line revenue -- not profit -- on the cartridges. I mean, we seem to be talking about hundreds of millions of dollars, and plaintiffs are suggesting they, they, they are going to make all this money. Smiths isn't making that type of money off of this product.

To continue the cartridge production, Smiths and plaintiffs point to this evidence. Smiths would have had to retool the mold. That's a $300,000 expense. They would have had to qualify new resin. That's about a $220,000 expense that the record shows.

So if you compare that to the revenues Smiths was making off of this product, the economics don't make it worth the while of Smiths to continue making the product but for the investment by United Therapeutics.

Now, if you look at the record, it is clear Smiths did

not try to keep a generic off the market in this instance. In 2016, it told Sandoz two or three times that MS®3 was going to be discontinued. In fact, one of our people told Sandoz that it doesn't make sense to bring a new drug to market on the back of a discontinued product. Sandoz ignored us. They went forward anyway. They took the position, we're a drug manufacturer. Devices are not our problem.

In 2019, when they found out they really had a problem, they came back to Smiths. Now, at that time all the cartridge production that was still available was contractually committed to United Therapeutics. It had been committed years before. But even though Smiths could not sell cartridges to the plaintiffs, it tried to help them. It offered them the CADD legacy pump. That's the pump that's used for IV infusion of Remodulin®, Your Honor. It has subcutaneous functionality.

Smiths also offered to license the cartridge technology, help them figure out the product specifications, know-how around product development and product manufacturing. They turned that down. We can't help that.

One thing is really clear. Smiths did not take any action here that kept this generic off the market. This is not an antitrust problem. Whatever problem it is, it's not an antitrust problem.

The one thing I will say, just to follow up on what Mr. Pitt said in response to plaintiff's counsel's argument, there

seems to be some suggestion here that the plaintiffs are really taking it on the chin in terms of price. Our economist in his expert report has some facts in there that show that in this environment, the brand of generic are being reimbursed by payers, Medicare, Medicaid payers, at the same rate.

They also have a slide in here on page 14 of their slide deck showing that the brand actually lowered the amount of co-pay for the patient. So we actually may be in a situation now where the patient today may be paying less for the brand than the generic.

So that is one final point. So with that, Your Honor, for defendants, we'd just ask that you deny the preliminary injunction. We also urge Your Honor to take a look at our motion to dismiss and grant that as well. If there are no further questions or any questions --

THE COURT: No. Thank you.

MR. BOYLE: Thank you.

MR. KENT: Good morning, Your Honor.

THE COURT: Welcome.

MR. KENT: Matthew Kent from Alston & Bird on behalf of the plaintiff Sandoz Inc. PowerPoint seems to be very popular today, so I have one to provide you as well.

THE COURT: Okay.

MR. KENT: Your Honor, the argument that Sandoz and RareGen were not diligent is nothing but an effort and

misdirection to misdirect this Court away from the defendant's conduct in this case from their efforts to block patients from a cheaper generic alternative. And there are two points that I want to walk the Court to that are specifically responsive to some of your questions that you posed to defendant's counsel as well as Mr. Glass.

First, I'm going to walk through the evidence that shows that Sandoz and RareGen were diligent in pursuing their launch of treprostinil. And second, I'm going walk through the timeline because I think it's critical that the Court understands when these restrictions were put in place because it shows that the free-riding argument that the defendants are setting forth doesn't make sense. It shows that the fact that the cartridges were not actually restricted at all for specialty pharmacies before 2019, it's something we actually agree on, and it also shows that the purpose and the intent of these arrangements was to block generic competition.

So let's start with Sandoz and RareGen's diligence. Now, I understand the diligence story. Your Honor correctly got to the crux in the initial questions that you were asking Mr. Glass. We have Sandoz and RareGen who produce the drug, and their customers, they are the specialty pharmacies. The specialty pharmacies here, they're the ones that provide the drug to patients, and they have always provided the cartridges and provided the pumps to patients.

And so when we think about the launch here, Sandoz and RareGen did exactly what you would expect a company to do. They went and they spoke to their customers at Accredo, and they asked them, what do we need to provide? And we see in August of 2017, on Exhibit 906, that Accredo confirmed -- I have it highlighted in yellow -- Accredo expects Sandoz to provide treprostinil vials only. And that's critical. That's diligence. Sandoz was going to its customers and it was asking, what do we need to provide, and it got an answer.

They also did the same thing with CVS. We did not cite this particular presentation in our brief, but Exhibit 907 is a CVS presentation that talks about how CVS SP will procure the pumps.

RareGen did the same thing. It talked to Accredo. It sent emails in May of 2018. That's Exhibit 314. It asks whether or not Accredo would have to provide pumps and cartridges or whether they, RareGen, would have to come up with those. And Accredo responded no. We handle the pumps.

THE COURT: Well, at that point, does your client know what's going on with Smiths?

MR. KENT: Well, Your Honor, I think this is a great effort at a sleight of hand in this direction because this is not a problem with the pump. So counsel for the defendants, they keep talking about the end-of-life notice that was sent in 2015 by Smiths, but that is an end-of-life notice for the

pumps. It is undisputed that that did not relate to cartridges. And, in fact, when you look at that end-of-life notice, you'll see that it talks about the cartridges being made for many years in the future. And in fact, we saw in the marketplace that the specialty pharmacies, Accredo and CVS, were able to continue to supply pumps and cartridges to patients. There was no reason for Sandoz and RareGen to think that UTC would use coercive, extreme measures to try to get those specialty pharmacies to agree to those restrictions.

And Mr. Glass didn't have a chance to go through, but if Your Honor would look at slide 3 of the PowerPoint presentation that Mr. Glass had, it has some of the salacious statements that the specialty pharmacies were going through. We're in serious need of product and will not be able to service our patients. This will have a significant impact on our patients. This is a huge risk to the patients. They were withholding cartridges that are needed, lifesaving medicines that are needed for patients in order to extract efforts to block the generic.

And I'll tell Your Honor, the most clear evidence of that blocking is cited in our brief. It's Exhibit 475. And it's on page 16 of our papers. It says, "We have a contract amendment from UTC that requires us to only sell to MS®3 cartridges to UTC designated customers. It is very important to UTC to prevent generic drug users."

And that's precisely what's happened. They have blocked generic drug users by creating a restriction so that specialty pharmacies cannot use those cartridges for patients with generic treprostinil.

I want to show one thing that we do agree on which is the timeline. It is undisputed in this case that Sandoz and RareGen didn't know of the cartridge restrictions until January of 2019. And let's put up the timeline. There are a lot of agreements in this case, Your Honor, and in fact, in reading the statement of facts, it can be hard to follow. So we created a timeline of these agreements.

Now, the defendants want you to believe that with the end-of-life notice that they were somehow diligent and that they came up with a path forward and were, in essence, free riding. That is simply not the case. The end-of-life notice came out before the first agreement was entered into. But ultimately, these agreements are not the most important ones in this case because they relate to pumps.

Now, if you go to the next slide, each of the agreements that I've marked an X over, they don't restrict the cartridges. The cartridge restrictions were not even done in January of 2019. They were done in April and in May of 2019. And so in January, when Sandoz, when RareGen first learned of the issue with the cartridge restrictions, they immediately spring into action. They immediately start to try to figure

out what is going on here. But before 2019, there were no cartridge restrictions on the specialty pharmacies. And that's critical.

We cite to the testimony of each of the Sandoz and RareGen's employees that confirm this point. That's on page 39 of our papers. And I want to show the Court just the initial pages of each of these agreements where there's finally the restriction. Because, again, April of 2019 is when that restriction comes into place.

Now, we can look also at the CVS, which is Exhibit 723, the May 2019 agreement.

Now, defendants, they -- the idea that a generic drugmaker would need to go out and develop and manufacture its own device, that's just wrong as a matter of fact and it's wrong as a matter of law. And Your Honor hit on a very critical point. It requires the Court to find that Sandoz would have or should have assumed that UTC was going to breach that patent settlement. And I want to take a look at that patent settlement because it's critical to this case.

So we have the settlement in September of 2015. It's Exhibit 1006, and it's clear, UTC was not to take any action, directly or directly, to prevent, delay, limit or otherwise restrict the launch.

Now, they keep pointing to a clause about the delivery devices, but that related to UTC-developed delivery devices.

There was no way for Sandoz and RareGen to know that UTC and Smith would get together and would sign agreements that effectively blocked the generic from entering the market by having these cartridge restrictions.

Now, the bottom line is that without UTC's blocking conduct, without the restrictions on the cartridges that weren't in place until April or May of 2019, Sandoz and RareGen would have brought a cheaper, lower cost generic to the market to serve subcutaneous patients. And as Mr. Glass said, it's important for us to be able to come to market and bring a product to reduce costs because that is what our companies are all about.

Now, Sandoz and RareGen did launch the IV. They chose in March of this year to launch in the IV space. And the reason they did that is because it's the right decision. It's the right decision morally. It's the right decision ethically. It's the right decision as a matter of law. And I'm sure that had Sandoz and RareGen decided not to launch in the IV space, UTC would have been thrilled because it would have continued. It would have allowed them to main their monopoly not just over the subcutaneous market through their blocking of the cartridges, but also over the IV space.

And, again, that, Your Honor, is just another diversion. It's another effort to try to avoid and misdirect the Court from the coercive and bad conduct of the defendants.

Your Honor, I'd like to provide the rest of my time to my co-counsel, Mr. Glass. Thank you.

MR. GLASS: Hello again, Your Honor.

THE COURT: How are you?

MR. GLASS: So with the last few minutes I would like to reflect upon what is not in dispute. What is not in dispute is as of today, there is no competitor to Remodulin® subcutaneous. As of today, the competition that RareGen and Sandoz bring to IV is severely impaired by the blocking of the subcutaneous route. As of today, UTC is making an incredible profit.

And I heard Smith's counsel say that they're innocent in all of this, but as we all know, they are a co-conspirator. They've engaged in overt acts. They are on the hook. Whatever contractual provisions they have between themselves are invalid and unenforceable. And they certainly can't be an excuse for engaging in any competitive conduct.

As of today, the defendants are blocking competition to the detriment of not only RareGen and Sandoz, but patients, prescribers, and payers.

They should not be allowed to benefit from that conduct. That's why the antitrust laws are here: To preserve competition. The only argument I really heard from defendants is that you should conflate pumps and cartridges. Because there was an end of life pump notice in 2015, we should assume

that everyone in the market knew the cartridges were going to be unavailable. But that's not consistent with the facts. As Mr. Kent noted, that end-of-life notice says in the end cartridges weren't end of life. And in fact, the cartridge end-of-life notice didn't come until this year.

Second, defendants are arguing that somehow their secret agreement to monopolize and extend the patent to block competition is something that we should have fixed. How can that be the standard in an antitrust case where the -- the plaintiffs not only need to somehow, without discovery, figure out what was going on, but then remedy it? We saw the slides about the alternative options. One option was new pumps. Two years. That's what the slide said. Two years. None of those are approved to be used in the United States. None can be approved for a long period of time.

We heard that all they want to do is serve Remodulin® patients. But Your Honor, the Remodulin® patients are everyone. So every patient we take, they don't need to serve.

As we heard from the president of the UTC, as well as many other witnesses, there is enough resin to make cartridges for ten years. There is no limit on cartridges except the limit that they've imposed on the specialty pharmacies to dispense them. This is not about them serving patients.

Finally, there's this notion that cartridges wouldn't exist but for the secret agreement. First, that's

self-serving testimony that doesn't match with the evidence. And Your Honor has plenty of evidence to review to see that that's just not true.

Smiths may have wanted to discontinue the pumps, but the cartridges are a different story. They didn't discontinue them. And Your Honor, as we engaged, if they had a problem with the profitability of the cartridges, the simple solution is to raise the price. In fact, had Smiths put the cartridges up for auction and said, look, UTC, bid against RareGen and Sandoz, they would have maximized the value of these cartridges. But instead, in a secret agreement, they sold them for pennies on the dollar. That's not our fault.

As we've said earlier today, if they're up for auction today, we would outbid UTC. That's how important these cartridges are to us.

So I don't want the distractions of all the timelines and all of the quotes to miss that today patients are losing out. And in fact, the patient assistance program shows exactly how they're losing out. It's not just that specialty pharmacies pay more. It's not just that insurers pay more. It's not just that Medicare and Medicaid pay more. All those should matter. It's that patients pay more.

Your Honor, this is a very important case. There are not a lot of people who take these, but those who do, it costs an incredible amount of money.

THE COURT: Okay.

MR. GLASS: Thank you, Your Honor.

THE COURT: Thank you.

Counsel.

MR. PITT: If Your Honor would permit me just a quick moment to respond to some of those points.

THE COURT: Sure.

MR. PITT: That would be wonderful. Thank you. I'll be very brief, Your Honor.

First, I wanted to point out that Mr. Kent pointed to an email from August 10th, 2017, in which Accredo said all you need to do is just give us the vials. I wanted to point out that there is another part of that timeline which is -- this is in our papers, but Sandoz had gotten a report from McKinzie that said due to the pump issues, there's a substantial chance of a delayed launch.

Sandoz then, in December of 2017, shut down its launch. They suspended it for those reasons. So the idea that that one Accredo email somehow gave them all of the certainty they needed in order to do a complex and very expensive launch like this doesn't really match with the evidence.

The end-of-life notice point, the end-of-life notice did pertain to cartridges. It -- what it states is that there will be enough cartridges to serve the then extent pumps. That is another three years.

The contemporaneous documents, which we've cited in our papers, demonstrate that had there been no restriction on the use of those cartridges, those cartridges only would have lasted until February 2019. That is a month before Sandoz and RareGen decided to launch. It was only through the Remodulin® only restrictions that they were projected to last until 2022 at the outset.

The point about the supposedly coercive and extreme tactics taken with the specialty pharmacies, Your Honor, I would only say that their quotes are extremely selective. There is -- it is completely undisputed that every order for cartridges placed by a specialty pharmacy was fulfilled. Every single one. There was no denial of any order of cartridges. The witnesses testified that there were no threats. And, in fact, the witness who negotiated with the specialty pharmacies, not for the contract between Smiths and the specialty pharmacies, which were not never even executed, which they're talking about, but the United Therapeutics' contracts with the specialty pharmacies, he testified that there were absolutely no problems. They opted not to depose anyone from the specialty pharmacy. And I think it's fair to ask why that is.

Just a couple of other points. The -- what they say they want to do, they want to ask you to look at the aspects of the arrangement between Smiths and United Therapeutics that

they don't like and to condemn those without looking at the overall arrangement that existed and that the contemporaneous evidence shows always existed between those two parties. The law doesn't permit that kind of disaggregation of an economic relationship when analyzing the economic or competitive effects of it. And the evidence doesn't support that.

The settlement clause that says there is no entitlement to a delivery mechanism does reference other pumps made by third parties and delivery mechanisms made by third parties. And the -- I guess those are the primary points I wanted to address. Thank you, Your Honor.

THE COURT: Counsel, thank you very much.

I will permit a five-page closing, if you will. I was going to say 14 days, but that's a horrible end date. So seven. This way at least you can have a week and hopefully not focus on this case.

MR. BENNETT: Seven days. The 17th.

THE COURT: Let's see. Ten?

MR. GLASS: Your Honor, I mean, it's a long time for these cartridges to be unavailable.

THE COURT: Okay. You want three?

MR. GLASS: I don't speak for Sandoz, but we'll be prepared to submit as quickly as Your Honor can take it.

THE COURT: Seven?

MR. BENNETT: Seven is fine with us.

THE COURT: Seven. Okay. Anything further?

MR. GLASS: Thank you, Your Honor.

THE COURT: Counsel, thank you very much. Wonderful job in papers and verbally today. Enjoy the holidays as best you can. Thank you.

THE DEPUTY COURT CLERK: All rise.

(Court concludes at 12:33 p.m.)

FEDERAL OFFICIAL COURT REPORTER'S CERTIFICATE.

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I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

I

/S/ Megan McKay-Soule, RMR, CRR **December 11, 2019**

Court Reporter Date

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